



July 27, 2020

Merit Medical Systems, Inc.  
Susan Christensen  
Principal Regulatory Affairs Specialist  
1600 West Merit Pkwy.  
South Jordan, Utah 84095

Re: K132155

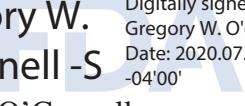
Trade/Device Name: Merit ASAPLP Aspiration Catheter  
Regulation Number: 21 CFR 870.5150  
Regulation Name: Embolectomy catheter  
Regulatory Class: Class II  
Product Code: QEZ

Dear Susan Christensen:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated November 7, 2013. Specifically, FDA is updating this SE Letter because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075,  
[Gregory.OConnell@FDA.HHS.gov](mailto:Gregory.OConnell@FDA.HHS.gov).

Sincerely,

  
**Gregory W.  
O'Connell -S**

Digitally signed by  
Gregory W. O'Connell -S  
Date: 2020.07.27 08:18:30  
-04'00'

Gregory O'Connell  
Assistant Director  
Plaque Modification Devices Team  
DHT2C: Division of Coronary  
and Peripheral Intervention Devices  
OHT2: Office of Cardiovascular Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health



## DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

November 7, 2013

Merit Medical Systems, Inc.  
% Susan Christensen  
Principal Regulatory Affairs Specialist  
1600 West Merit Pkwy.  
South Jordan, UT 84095 US

Re: K132155  
Trade/Device Name: Merit ASAPLP™ Aspiration Catheter  
Regulation Number: 21 CFR 870.5150  
Regulation Name: Embolectomy Catheter  
Regulatory Class: Class II  
Product Code: DXE  
Dated: October 9, 2013  
Received: October 10, 2013

Dear Ms. Christensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman". To the right of the signature is a small, faint watermark-like logo for the FDA, consisting of the letters "FDA" in a stylized font.

for Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

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**Section 4**  
**Indications for Use**

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510(k) Number (if known): K132155

Device Name: Merit ASAPLP™ Aspiration Catheter

**Indications for Use:**

The Merit ASAPLP Aspiration Catheter is intended for the removal of fresh, soft emboli and thrombi from vessels of the arterial system.

Not for use in cerebral vasculature.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



M. G. Hillebrecht

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## Section 5

### 510(k) Summary

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<b>General Provisions</b>	Submitter Name: Merit Medical Systems, Inc. Address: 1600 West Merit Parkway South Jordan, UT 84095 Telephone Number: (801) 208-4789 Fax Number: (801) 253-6919 Contact Person: Susan Christensen Date of Preparation: July 11, 2013 Registration Number: 1721504
<b>Subject Device</b>	Trade Name: Merit ASAPLP™ Aspiration Catheter Common/Usual Name: Embolectomy Catheter Classification Name: Embolectomy Catheter
<b>Predicate Device</b>	Trade Name: ASAP® Aspiration Catheter Classification Name: Embolectomy Catheter Premarket Notification: K100569 Manufacturer: Merit Medical Systems, Inc.
<b>Classification</b>	Class II 21 CFR § 870.5150 FDA Product Code: DXE Review Panel: Cardiovascular
<b>Intended Use</b>	The Merit ASAPLP Aspiration Catheter is intended for the removal of fresh, soft emboli and thrombi from vessels of the arterial system.  Not for use in cerebral vasculature.
<b>Device Description</b>	The ASAPLP Aspiration Catheter is a dual lumen rapid exchange catheter, compatible with 0.014"/0.36mm guide wires. It is packaged with related accessories including a stiffening stylet. The catheter has a maximum outer diameter of 0.055"/0.140cm and a working length of 145cm. The catheter has a radiopaque marker band located approximately 2mm proximal to the distal tip. The catheter has three (3) non-radiopaque positioning marks located approximately 90cm, 100cm and 110cm proximal of the distal tip. The distal region has a hydrophilic coating. The rapid exchange lumen is 20cm in length.

**Comparison to  
Predicate  
Device**

The technological characteristics of the subject Merit ASAPLP Aspiration Catheter are substantially equivalent to those of the predicate device. The Merit ASAPLP Aspiration Catheter has a smaller outer diameter than the predicate ASAP Aspiration Catheter. In addition, the design of the Merit ASAPLP Aspiration Catheter is slightly different and includes a round aspiration lumen instead of "U" channel aspiration lumen with several material changes. Also, the length of the Rapid Exchange Lumen is increased, and a stiffening stylet is added which can be used during insertion of the catheter.

No applicable mandatory performance standards or special controls have been established under Section 514 of the Food, Drug and Cosmetic Act for these devices. However, a battery of tests was performed according to protocols based on the requirements of industry standards and the device risk analysis and the device met the acceptance criteria necessary to demonstrate the safety and efficacy of the device.

Where appropriate, the tests were based on the requirements of the following documents:

- ISO 10555-1: 1995, *Sterile, single-use intravascular catheters – Part 1: General requirements*
- ISO 594-1:1986, *Conical Fittings with a 6% (Luer) taper for syringes, needles, and certain other medical equipment – Part 1: General Requirements*
- ISO 594-2:1998, *Conical Fittings with a 6% (Luer) taper for syringes, needles, and certain other medical equipment – Part 2: Lock fittings*
- EN 13868: 2002, *Test methods for kinking of single lumen catheters and medical tubing*
- ISO 11135-1: 2007, *Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*
- ASTM F640-12, *Standard Test Methods for Determining Radiopacity for Medical Use*
- ASTM F756-08, *Standard Practice for Assessment of Hemolytic Properties of Materials*
- ISO 10993-1: 2009, *Biological Evaluation of Medical Devices Part-1: Evaluation and Testing within a risk management process*
- ISO 10993-3: 2003, *Biological Evaluation of Medical Devices Part-3: Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity*
- ISO 10993-4: 2002, *Biological Evaluation of Medical Devices Part-4: Selection of Tests for Interactions with Blood, as amended 2006*
- ISO 10993-5: 2009, *Biological Evaluation of Medical Devices*

**Safety &  
Performance  
Tests**

**Safety &  
Performance  
Tests  
(Continued)**

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- *Part-5 Tests for In Vitro Cytotoxicity*
  - ISO 10993-7: 2008, *Biological Evaluation of Medical Devices Part-7 Ethylene Oxide Sterilization Residuals*
  - ISO 10993-10: 2010, *Biological Evaluation of Medical Devices Part-10 Tests for Irritation and Skin Sensitization*
  - ISO 10993-11: 2006, *Biological Evaluation of Medical Devices Part-11 Tests for Systemic Toxicity*
  - USP 35-151: 2012, *United States Pharmacopeia 35, National Formulary 30, 2012 <151> Pyrogen Test*

The following is a list of all significant testing performed on the ASAPLP. All testing was successfully completed.

Surface Condition / Visual  
Corrosion Resistance  
Force at Break  
Catheter Liquid Leak under Pressure  
Catheter Air Aspiration Leak  
Dimensions  
Luer Gauging Test  
Luer Liquid Leak Test  
Luer Air Aspiration Leak Test  
Luer Separation Force Test  
Luer Unscrewing Torque Test  
Luer Ease of Assembly Test  
Luer Resistance to Overriding Test  
Luer Stress Cracking Test  
Radio-Detectability  
Kink  
Stiffness  
Aspiration  
Flow  
Coating Lubricity and Coverage  
Marker Band Retention  
Guide Wire Friction Test  
Simulated Use Test in Anatomical Model  
Simulated Aspiration and Use Test in Tortuous Path Model

Biocompatibility Tests

Cytotoxicity  
Sensitization  
Irritation  
Acute Systemic Toxicity  
Rabbit Pyrogen Test  
Genotoxicity  
Hemocompatibility  
Physicochemical Tests

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**Summary of  
Substantial  
Equivalence**

Based on the indications for use, design, and safety and performance testing, the subject Merit ASAPLP Aspiration Catheter meets the requirements that are considered essential for its intended use and is substantially equivalent to the predicate device, the ASAP Aspiration Catheter (K100569), manufactured by Merit Medical Systems, Inc.

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